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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,858	01/23/2002	Jeffrey S. Bland	METAG.027A	3800

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/056,858

Applicant(s)

BLAND ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/04/2003 as Paper Number 8.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 81 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5&6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' response filed March 04, 2003 as Paper Number 8 to election requirement in Office Action mailed January 27, 2003 as paper number 7 is acknowledged and entered.

Restriction/Election

2. Applicants' election without traverse of Group I, Claims 1-80 filed March 04, 2003 as Paper Number 8 to election requirement in Office Action mailed January 27, 2003 as paper number 7 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 81-82 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 1-80 are examined on merits.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. Based upon filing of U.S. Provisional Application Number 60/265,908, instant non-provisional U. S. Application Number 10/065,858 is given the benefit of filing date of February 02, 2001.

Information Disclosure Statement

5. Applicants' Information Disclosures (i.e., IDSs) filed July 02, 2002 as paper number 4, July 06, 2002 as paper number 5 and on July 23, 2002 as paper number 6 have been made of record and considered.

Claims Objection

6. Claims 38-39 and 78-79 are objected to because phrase, "is at least compound selected" is grammatically incorrect and incomplete. Appropriate correction is requested.

Claim Rejections - 35 U.S.C. § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-80 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrase "isoflavone synergist" in claims 1, 13, 14, 41, 47-48, 52 and 56 renders those claims indefinite because it is not clear what is meant by the phrase "isoflavone synergist". The metes and bounds for the said phrase are not defined. Applicants should clarify the phrase "isoflavone synergist".
- The phrase "methylation support compound" in claims 1, 19, 22, 25, 41, 60-61, 64 and 67 renders those claims indefinite because it is not clear what is meant by the phrase "methylation support compound". The metes and bounds for the said phrase are not defined. Applicants should clarify the phrase "methylation support compound".
- The recitation, "derivative" in claims 5,8-9, 18,25-30,33,33-34, 42-43, 62, 67-72 and 74 renders those claims unclear as well as confusing, and therefore indefinite because the term does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter. Applicants are requested to define and clarify the recitation "derivative".
- The phrase "lipid modulator" in claims 6-7 renders those claims indefinite because it is not clear what is meant by the phrase "lipid modulator". The metes and bounds for said phrase are not defined. Applicants should clarify the phrase "lipid modulator".

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have

been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

11. Claims 1-80 are rejected under 35 U.S.C. § 103 (a) as obvious over Cope (U.S. Patent 5,330,972) in view of Clark et al. (U.S. Patent 5,837,256) and Yang et al. (U.S. 2002/0025360).

Claims recite a composition comprising macro and micronutrients, wherein macronutrients comprise, carbohydrates, lipids and protein and the micronutrients are: isoflavone, isoflavone synergist, methylation support compound for estrogen metabolites, minerals, vitamins, dietary fiber, fortifying amino acids, carotenoid and flavonoid.

Cope teaches a composition comprising fructose, sucrose, canola oil, choline, soy polysaccharides/protein hydrolysate, cobalamin, folic acid, lysine, threonine, beta carotene, calcium, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, sodium, selenium, zinc, vitamins: A, C, D, E, K, biotin, cyanocobalamin, folic acid, pyridoxine, riboflavin and thiamin (Column 5, Lines 40-68; Column 6, Lines 10 and 13; Column 8, Line 6; Column 9, Lines 56-58; Column 14, Line 28, Tables 7 and 8). Thus, Cope teaches a composition comprising all the ingredients of claimed invention except for sources of dietary fiber, flavonoid and isoflavone synergist.

Clark et al., however, teach a composition comprising flaxseed lignan (Column 3, Lines 1-4, Tables 1 and 2). Please note that the prior art reference is teaching the same source and same component obtained from said source (i.e., lignan from flaxseed) as is recited in the claimed invention. Thus, the prior art intrinsically teaches a source of dietary fiber in their composition, wherein said dietary fiber is obtained from flaxseed lignan.

None of the references cited *supra* teach a composition comprising curcumin, lycopene, hesperidin or quercetin.

Yang et al. teach a food composition comprising curcumin, lycopene, hesperidin or quercetin (Page 5, Column 1, Paragraph 35, Lines 5-19).

- Please note that despite the fact that compositions disclosed in the Examiner-cited prior art references do not refer to "a medical food for treating hormone imbalance", the claims remain obvious to an artisan of ordinary skill because the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight.

An artisan of ordinary skill would be motivated to combine the teachings from each one of the cited references because each one of the cited prior art references teach a composition comprising macronutrient and micronutrient components recited in the claimed invention. While, Clark et al. remedy the deficiency of flaxseed lignan as the source of dietary fiber (Column 3, Lines 1-4, Tables 1 and 2) in Cope's composition (Column 5, Lines 40-68; Column 6, Lines 10 and 13; Column 8, Line 6; Column 9, Lines 56-58; Column 14, Line 28, Tables 7 and 8), Yang et al. remedy the deficiencies of curcumin, lycopene, hesperidin or quercetin (Page 5, Column 1, Paragraph 35, Lines 5-19) in teachings from Cope and Clark et al.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Cope according to the teachings from Clark et al. to incorporate flaxseed lignan as the source of dietary fiber and further incorporate Yang et al's teachings to incorporate curcumin, lycopene, hesperidin or quercetin, because each one of the cited prior art reference teach a composition comprising macro and micronutrients.

None of the above discussed prior art references teach rice flour or rice protein as the protein source. kudzu root as source of isoflavone or the same quantities of isoflavone, isoflavone synergists, methylation support compounds. However, the adjustment of particular conventional working conditions (e.g., the quantities of each one of components or sources of those components, pH, temperature etc.) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

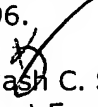
Conclusion

12. No Claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

May 19, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER